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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,443	05/23/2006	Joachim Moormann	RO4245US (#90568)	2527

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,443	MOORMANN ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-6,16,17,21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-15, 18-20 and 23-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicants have amended the claims to overcome the 35 USC 101 and 112 rejections and the rejections are hereby withdrawn.

Applicants argue over the 35 USC 102(b) rejection that the Vonin et al. reference does not teach each and every limitation of the presently claimed invention. In particular, Applicants argue that the patients in the Vonin et al. reference do not show any signs of psychosis and do not describe the treatment of patients suffering from schizophrenic psychosis.

As Applicants have stated in their specification, schizophrenia is a psychiatric illness (psychosis) which is accompanied by changes in thinking, perception and behavior (paragraph 0003 in the specification). In addition to that, Applicants describe addition symptoms of schizophrenic psychosis which are blocking of thought processes, disorders of emotional life and drive, loss of reality and the "ego disorder". That being said, it is understood that the general definition of schizophrenia given by Applicants is the general understanding of schizophrenia. Accordingly, a patient with schizophrenia has psychosis. Further, Vonin et al. describe that the clinical pattern as a whole for the patient population involved a decreased or absent initiative and emotional detachment, which fall in line with Applicants description of symptoms of schizophrenic psychosis. Though Vonin et al. may not use the terminology of schizophrenic psychosis, it is noted that schizophrenia is marked by psychosis by changes in thinking and perception and

the symptoms described by Applicant's in their specification overlap with that taught in Vonin et al.

Applicants also argue that Vonin describes the use of a combination of an anticholinesterase agent (deoxypeganine) with a M-cholinolytic drug, which is argued that the reference differs from the present invention in regards to the choice of active agents. It is noted that the present claims are drawn to a method for treating schizophrenic psychosis with the method comprising administration of deoxypeganine. The language of the claims uses 'comprising' language which is open-ended and allows for the inclusion of other elements (MPEP 2111.03). Therefore, the prior art does read on the present claims as written.

Applicants assert that the reference does not describe a relief of symptoms in the two patients that were administered a combination of deoxypeganine and amizil. However, the results describe that 18 out of 30 subjects (including the two that received deoxypeganine and amizil) exhibited indisputable and completely satisfactory compensation for the deficitary symptoms. Therefore, there is no specific teaching that the combination of deoxypeganine and amizil was not effective.

Applicants put forth the same arguments over the 35 USC 103 rejection and the same response to the arguments is put forth as well.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 rejected under 35 U.S.C. 102(b) as being anticipated by Vonin et al. (Stvo Meditsina; Moscow, Russia; Vo. 91, No. 2 (Feb. 1991), pages 111-115).

Vonin et al. teach the treatment of schizophrenic patients with deoxypeganine (see Abstract, and page 115).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-15, 18-20 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vonin et al. (Stvo Meditsina; Moscow, Russia; Vo. 91, No. 2 (Feb. 1991), pages 111-115) as applied to claim 7 above and in view of Opitz et al. (US Pg-Pub 2004/0132751)

Vonin et al. teaches the treatment of schizophrenic patients with deoxypeganine.

Vonin et al. does not teach a daily dose, the proportions of the active substance in a pharmaceutical, route of administration.

Opitz et al. teaches the use of deoxypeganine for the treatment of disorders of CNS, including psychiatric symptoms (paragraph 0001). It is taught that deoxypeganine can be used in its free base form or as an acid addition salt, with preferred salt being

deoxypeganine hydrochloride and hydrobromide (paragraph 0015). Opitz et al. teaches that deoxypeganine is administered in a pharmaceutical preparation which contains the agent in proportions of from 0.1 to 90% by weight calculated as free deoxypeganine (paragraph 0016). The daily dose is in the range from 0.1 to 100 mg (paragraph 0017). It is taught that deoxypeganine can be administered orally, parenterally, as a depot medicament (paragraph 0031) and transdermally (paragraph 0031).

Regarding the claims limitation of administration of the deoxypeganine being in the form of a derivative, as in claim 15, it is noted that the derivatives are structurally analogous to deoxypeganine and will have the same property of inhibiting both acetylcholinesterase and monoamine oxidase, absent a showing of unexpected results.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
Primary Examiner, Art Unit 1627

Renee Claytor